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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,389	03/30/2004	S. Raghukumar	056859-0198	1738
22428	7590	06/26/2006		EXAMINER
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			FERNANDEZ, SUSAN EMILY	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/812,389	RAGHUKUMAR ET AL.
	Examiner Susan E. Fernandez	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/12/04, 3/31/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7 are pending and examined on the merits.

Oath/Declaration

In the Declaration filed October 12, 2004, it is noted that the name of one of the inventors was typewritten as S. Raghukumar, which differs from the inventor's signature (S. Raghu Kumar), and thus appears to be a typographical error. When a typographical or transliteration error in the spelling of an inventor's name is discovered during pendency of an application, a petition is not required, nor is a new oath or declaration under 37 CFR 1.63 needed. However, applicants are strongly encouraged to use an application data sheet such that any patent to issue will reflect the correct spelling of the inventor's name. Without an application data sheet with the corrected spelling, any patent to issue is less likely to reflect the correct spelling since the spelling of the inventor's name is taken from the oath or declaration, or any subsequently filed application data sheet.

Information Disclosure Statement

A third-party submission has been filed under 37 CFR 1.99 on March 31, 2005 in the published application.

To ensure that a third-party submission does not amount to a protest or pre-grant opposition, 37 CFR 1.99 does not permit the third party to have the right to insist that the examiner consider any of the patents or publications submitted. Furthermore, if the submission or part of the submission is not in compliance with 37 CFR 1.99, that noncompliant submission

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or part thereof will not be entered in the application file. Therefore, unless the examiner clearly cites a patent or publication on form PTO-892, Notice of References Cited and such reference is used in a rejection or its relevance is actually discussed during prosecution, consideration by the examiner of any patent or publication submitted in a third-party submission cannot be presumed.

If the applicant wants to ensure that the information in a third-party submission is considered by the examiner, the applicant should submit the information in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98. An individual who has a duty to disclose under 37 CFR 1.56 should also submit any material information contained in a third-party submission to the Office in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98 to ensure such material information is properly disclosed to the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the thrausochytrid protists deposited under accession numbers MTCC 5121, 5122, and 5123 are recited in parent claim 1, they are essential to the invention recited in that claim. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be

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readily available to the public. If the microorganisms are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not apparent if the microorganisms are readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b), which states:

- (b) A viability statement for each deposit of a biological material defined in paragraph (a)

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of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since the recitation of “the same” in steps (a) and (b) is confusing. It is unclear what is referred to by “the same.” Additionally, claim 1 is indefinite since the recitation “obtaining the cultures thus grown” in step (b) is confusing. Only a single culture would have been grown by performing step (a), therefore it is suggested that “the cultures thus grown” be replaced with “the culture thus grown.” Claims 1-7 are thus rejected under 35 U.S.C. 112, second paragraph.

Claims 2 and 3 are indefinite since the recitation “wherein step (a or b), the culture medium...” is unclear. It is suggested that “wherein step...” be replaced with “wherein in step...” Thus, claims 2-7 are rejected under 35 U.S.C. 112, second paragraph.

Claim 3 is rendered indefinite by the recitation “the culture medium” at line 1, since the phrase lacks antecedent basis. Parent claim 1 recites “a medium” instead of a “culture medium.” Thus, claims 3-7 are rejected under 35 U.S.C. 112, second paragraph.

Claim 4 is rendered indefinite by the recitation “the culture” since “the culture” would comprise only of the organisms grown on a culture medium. It appears that “the culture” recited in the claim is a “culture medium” or “medium.” Additionally, it is not clear whether the culture medium defined in claim 4 is the culture medium of step (a) or the medium of step (b) in claim 1.

Claims 5-7 are rendered indefinite by the recitation “said culture medium.” It is not clear whether “said culture medium” is the “culture medium” recited in step (a) of claim 1, or the “medium” recited in step (b) (which is referred to as a “culture medium” in claim 3). Thus, claims 5-7 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. § 102(b), (e), and (a) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kumar et al. (WO 01/73099) or US 6,410,282.

Kumar et al. discloses a method wherein a “culture of a candidate species of the thraustochytrid fungus, which contains the omega-3 PUFAs DHA [docosahexaenoic acid] and EPA [eicosapentaenoic acid] is first inoculated into a liquid nutrient medium” (page 6, lines 17-19). Moreover, strains of fungi belonging to “other thraustochytrid fungi” such as a number of strains of the *Thraustochytrium* genus, may also be used (page 6, lines 19-23). The culture is

grown for two days at 25 to 30°C (page 6, lines 26-27), and this first step meets the limitations as recited in step (a) of instant claim 1. Note that the culture medium for this step is a culture medium comprising peptone, yeast extract, glucose, and sea water (page 6, lines 10-16) at the same concentrations/amounts recited in instant claims 2-7.

Next, this culture is used as an inoculum to inoculate a medium with enhanced viscosity (page 6, line 27 through page 7, line 1), wherein the medium further comprises polyvinyl pyrrolidone at concentrations of 0.1 to 1.0% (page 7, lines 1-9), which meets the concentration limitations recited in instant claims 3 and 4. This step meets the limitations recited in step (b) of instant claim 1. Furthermore, the culture is grown in the medium with enhanced viscosity for 2-7 days at 25-30°C (page 7, lines 11-13), thus meeting limitations recited in step (c) of instant claim 1. Afterwards, the culture is harvested, and extraction of pure DHA and EPA from the harvested cell biomass may be performed (page 7, lines 13-17), which reads on the limitations recited in step (d) of instant claim 1. Kumar et al. points out that “the present invention thus relates to a process to enhance the levels of the omega-3 PUFAs, DHA and EPA” (page 7, lines 18 and 19). Clearly, Kumar et al. teaches the same steps for accomplishing the same purpose as recited in the claims under examination.

Though Kumar et al. does not specify that any of the *Thrausochytrium* strains disclosed in the reference from which DHA and EPA (page 6, lines 19-23) are deposited under the accession number MTCC 5122, the strains of *Thrausochytrium* disclosed in Kumar et al. appear to be identical to the presently claimed strain, based on the fact that the prior art strains are members of the same genus, the prior art strains produce DHA and EPA, and since the steps recited in the instant claims are suitable for enhancing the levels of DHA and EPA from the

strains of *Thrausochytrium* protists disclosed in Kumar et al. Consequently, the claimed strain of *Thrausochytrium* protist and methods of enhancing the level of DHA and EHA in said *Thrausochytrium* protist appears to be anticipated by the references.

However, even if the Kumar et al. strains and the claimed strain are not one and the same and there is, in fact, no anticipation, the strains disclosed by the references would, nevertheless, have rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the reference disclose members of the same genus as that claimed, the prior art strains produce DHA and EPA, and since the steps recited in the instant claims are suitable for enhancing the levels of DHA and EPA from the strains of *Thrausochytrium* protists disclosed in Kumar et al. Moreover, one of ordinary skill in the art would have been motivated to have performed the methods of Kumar et al. using any other thrausochytrid fungi since Kumar et al. indicates that “strains of fungi belonging to other thraustochytrid fungi...may also be used” (page 6, lines 19-23). Thus, the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Note that US 6,410,282 teaches the same invention as Kumar et al. (column 3, lines 59-67; column 4, lines 1-41).

Claim Rejections - 35 USC § 103

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. in view of Yokochi et al. (Appl. Microbiol. Biotechnol. 1998. 49: 72-76).

As discussed above Kumar et al. anticipates claims 1-7 when the levels of DHA and EPA are enhanced in thraustochytrid protist belonging to the genera *Thraustochytrium* deposited under the accession number MTCC 5122. However, Kumar et al. does not disclose increasing DHA and EPA levels in thrausochyrid protists belonging to the genera *Schizochytrium*.

Yokochi et al. discloses a strain of *Schizochytrium* which produces DHA and icosa-pentaenoic acid (also known as eicosapentaenoic acid, EPA) (abstract).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have performed the methods of Kumar et al. on the *Schizochytrium* protist of the strain disclosed in Yokochi et al. One of ordinary skill in the art would have been motivated to do this since Kumar et al. indicates that “strains of fungi belonging to other thraustochytrid fungi...may also be used” (page 6, lines 19-23), and since the *Schizochytrium* protist disclosed in Yokochi et al. is a thraustochytrid fungi which produces both DHA and EPA. There would have been a reasonable expectation of success in applying the methods of Kumar et al. to any other thraustochytrid fungi.

It is further pointed out that the strain of *Schizochytrium* disclosed in Yokochi et al. appears to be identical to the presently claimed strain of *Schizochytrium*, based on the fact that the prior art strains are members of the same genus, and the prior art strain produces DHA and EPA. Consequently, the claimed strain of *Schizochytrium* protist and methods of enhancing the level of DHA and EHA in said *Schizochytrium* protist appears to be anticipated by the references.

However, even if the Yokochi strain and the claimed strain are not one and the same and there is, in fact, no anticipation, the strain disclosed by the references would, nevertheless, have

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rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the reference discloses a member of the same genus as that claimed, and the prior art strain produces DHA and EPA. Thus, the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Additionally, Kumar et al. differs from the claimed invention in that Kumar et al. does not disclose enhancing DHA and EPA levels in thrausochyrid protists belonging to the genera *Aplanochytrium*.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have performed the methods of Kumar et al. on any other thraustochyrid protist, including any strain of the *Aplanochytrium* genus. One of ordinary skill in the art would have been motivated to do this since Kumar et al. indicates that “strains of fungi belonging to other thraustochyrid fungi...may also be used” (page 6, lines 19-23). There would have been a reasonable expectation of success in applying the methods of Kumar et al. to any other thraustochyrid fungi.

A holding of obviousness is clearly required.

Double Patenting

Claims 1-7 are directed to an invention not patentably distinct from claims 1-6 of commonly assigned US Pat. 6,410,282. Specifically, the claims under examination recite the same steps as recited in the patented claims, but require using different strains of thrausochyrid fungi.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Pat. 6,410,282, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,410,282 in view of Yokochi et al. As pointed out above, the claims under examination recite the same steps as recited in the patented claims, but require using different strains of thraustochytrid fungi. Yokochi et al. teaches that a strain of *Schizochytrium* produces docosahexaenoic acid and eicosapentaenoic acid (abstract), as do protists of the *Thraustochytrium* genus (page 76, first paragraph). It would have been obvious to have substituted the specific thraustochytrid fungus recited in '282 with any other thraustochytrid fungus disclosed in the prior art, such as those in Yokochi et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER